

General

Title

Androgen deficiency: percentage of male patients aged 18 years and older with androgen deficiency who are receiving testosterone therapy, who have a baseline gonadotropin (LH or FSH) measurement performed within six months prior to initiating testosterone therapy.

Source(s)

Endocrine Society. Diagnosis, treatment, and follow-up of men with androgen deficiency. Physician performance measurement set. Washington (DC): Endocrine Society; 2012 May. 17 p. [31 references]

Measure Domain

Primary Measure Domain

Clinical Quality Measures: Process

Secondary Measure Domain

Does not apply to this measure

Brief Abstract

Description

This measure is used to assess the percentage of male patients aged 18 years and older with androgen deficiency who are receiving testosterone therapy, who have a baseline gonadotropin (luteinizing hormone [LH] or follicle-stimulating hormone [FSH]) measurement performed within six months prior to initiating testosterone therapy.

Rationale

In male patients with testicular failure, it is important to rule out secondary causes, such as pituitary insufficiency (Ascoli & Cavagnini, 2006; McClure, 1988). Measurement of gonadotropins is necessary for this (Lenzi et al., 2009). In men deemed to have secondary hypogonadism, initial diagnostic evaluation is needed to exclude pituitary adenoma, hyperprolactinemia, hemochromatosis and other infiltrative diseases, medications (e.g., opiates or glucocorticoids, and genetic disorders associated with

gonadotropin deficiency). In men taking chronic opiates, secondary hypogonadism is common, but the etiology should be confirmed with the measurement of serum luteinizing hormone (LH), with or without follicle-stimulating hormone (FSH). Secretion of LH and FSH by the pituitary is pulsatile which can result in some variability in serum levels. LH levels respond to and correlate more directly with androgen levels; however, FSH levels may be a more sensitive measure of testicular failure. Although measurement of both gonadotropins is encouraged by the Endocrine Society, measurement of either LH or FSH will be deemed sufficient for meeting this provider accountability measure.

Supporting Guideline:

The Endocrine Society recommends measurement of serum LH and FSH levels to distinguish between primary (testicular) and secondary (pituitary) hypogonadism. Men with primary hypogonadism have low testosterone levels in association with elevated LH and FSH levels, whereas men with secondary hypogonadism have low testosterone levels associated with low or inappropriately normal LH levels (Bhasin et al., 2010).

Evidence for Rationale

Ascoli P, Cavagnini F. Hypopituitarism. Pituitary. 2006;9(4):335-42. [PubMed](#)

Bhasin S, Cunningham GR, Hayes FJ, Matsumoto AM, Snyder PJ, Swerdloff RS, Montori VM, Task Force, Endocrine Society. Testosterone therapy in men with androgen deficiency syndromes: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2010 Jun;95(6):2536-59. [151 references] [PubMed](#)

Endocrine Society. Diagnosis, treatment, and follow-up of men with androgen deficiency. Physician performance measurement set. Washington (DC): Endocrine Society; 2012 May. 17 p. [31 references]

Lenzi A, Balercia G, Bellastella A, Colao A, Fabbri A, Foresta C, Galdiero M, Gandini L, Krausz C, Lombard G, Lombardo F, Maggi M, Radicioni A, Selice R, Sinisi AA, Forti G. Epidemiology, diagnosis, and treatment of male hypogonadotropic hypogonadism. J Endocrinol Invest. 2009 Dec;32(11):934-8.

McClure RD. Endocrine evaluation and therapy of erectile dysfunction. Urol Clin North Am. 1988 Feb;15(1):53-64. [PubMed](#)

Primary Health Components

Androgen deficiency; testosterone therapy; baseline gonadotropin (luteinizing hormone [LH]) or follicle-stimulating hormone [FSH]) measurement

Denominator Description

All male patients aged 18 years and older with androgen deficiency who are receiving testosterone therapy (see the related "Denominator Inclusions/Exclusions" field)

Numerator Description

Patients who have a baseline gonadotropin (luteinizing hormone [LH] or follicle-stimulating hormone [FSH]) measurement performed within six months prior to initiating testosterone therapy

Evidence Supporting the Measure

Type of Evidence Supporting the Criterion of Quality for the Measure

A clinical practice guideline or other peer-reviewed synthesis of the clinical research evidence

A formal consensus procedure, involving experts in relevant clinical, methodological, public health and organizational sciences

One or more research studies published in a National Library of Medicine (NLM) indexed, peer-reviewed journal

Additional Information Supporting Need for the Measure

In population-based surveys of middle aged and older men, symptoms of low libido, erectile dysfunction, hot flushes, fatigue, loss of vigor, irritability, depressed mood, impaired concentration, reduced physical performance, or sleep disturbance, were associated with low testosterone levels. In these surveys, the prevalence of symptomatic androgen deficiency was approximately 6% of the population of middle-aged to older men and increased with age, waist circumference and poor self-reported health status.

Hypogonadism is therefore common in American men, yet only 5% of candidates receive treatment.

According to U.S. Census Bureau (2004) projections, the number of Americans ages 65 or older will rise from approximately 35 million (12.4% of all Americans) in 2000 to nearly 55 million (16.3% of total) by 2020 and nearly 87 million (20.7%) in 2050. In addition to a two-fold increase in the number of elderly patients, octogenarians will comprise the fastest-growing population segment according to age (Batchelor, Jollis, & Friesinger, 1999).

This gap in care can profoundly affect the health of our aging men. Even in younger men with symptoms, infertility may be a consequence of androgen deficiency. Male infertility contributes to 50% of all infertility cases. However, both low testosterone and supraphysiologic androgen administration can lead to infertility. The impaired sperm production that supraphysiological testosterone administration causes is often reversible, but in some series has been shown to take anywhere from 3 months to years.

Inappropriate testosterone use is also a major concern of these times. In the sports arena, so far, 45 National Football League (NFL) players have had a ban or suspension placed on them. Among Major League Baseball players, 7% have tested positive for steroids. This inappropriate use has trickled down to the U.S. population. According to ProjectEAT, a five-year, longitudinal study, overall, 1.5% of adolescents reported using steroids (vandenBerg et al., 2007). In a 2002 study by Texas A&M University, it was estimated that up to 42,000 Texas students were abusing steroids.

It is important that testosterone be used to replace hormonal deficiency, and not be used inappropriately in pharmacological doses for enhancement of physical performance or muscular size. The testosterone process measures listed here will assist us to prescribe testosterone to only those individuals in whom it is medically indicated.

Because the diagnosis and management of androgen deficiency in men poses several challenges (symptoms and signs are nonspecific and modified by age, comorbid illness, severity and duration of androgen deficiency, variation in androgen sensitivity, and previous testosterone therapy; evidence of proper care is weak; long-term health consequences of low testosterone levels are unknown for older men and men with chronic illness; the impact of untreated androgen deficiency on mortality is unclear; the benefits and adverse effects of long-term testosterone therapy on patients are not known), these performance measures were determined to be of critical importance to standardize care as outlined in the clinical guidelines.

Evidence for Additional Information Supporting Need for the Measure

Batchelor WB, Jollis JG, Friesinger GC. The challenge of health care delivery to the elderly patient with cardiovascular disease. Demographic, epidemiologic, fiscal, and health policy implications. *Cardiol Clin.* 1999 Feb;17(1):1-15, vii. [PubMed](#)

Endocrine Society. Diagnosis, treatment, and follow-up of men with androgen deficiency. Physician performance measurement set. Washington (DC): Endocrine Society; 2012 May. 17 p. [31 references]

U.S. Census Bureau. 2004 interim national population projections. [internet]. Washington (DC): U.S. Census Bureau; 2004 [accessed 2005 Jan 25].

vandenBerg P, Neumark-Sztainer D, Cafri G, Wall M. Steroid use among adolescents: longitudinal findings from Project EAT. *Pediatrics.* 2007 Mar;119(3):476-86. [PubMed](#)

Extent of Measure Testing

Unspecified

State of Use of the Measure

State of Use

Current routine use

Current Use

not defined yet

Application of the Measure in its Current Use

Measurement Setting

Ambulatory/Office-based Care

Professionals Involved in Delivery of Health Services

not defined yet

Least Aggregated Level of Services Delivery Addressed

Individual Clinicians or Public Health Professionals

Statement of Acceptable Minimum Sample Size

Unspecified

Target Population Age

Age greater than or equal to 18 years

Target Population Gender

Male (only)

National Strategy for Quality Improvement in Health Care

National Quality Strategy Aim

Better Care

National Quality Strategy Priority

Prevention and Treatment of Leading Causes of Mortality

Institute of Medicine (IOM) National Health Care Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Data Collection for the Measure

Case Finding Period

Unspecified

Denominator Sampling Frame

Patients associated with provider

Denominator (Index) Event or Characteristic

Clinical Condition

Patient/Individual (Consumer) Characteristic

Therapeutic Intervention

Denominator Time Window

not defined yet

Denominator Inclusions/Exclusions

Inclusions

All male patients aged 18 years and older with androgen deficiency who are receiving testosterone therapy

Note: Refer to the original measure documentation for International Classification of Diseases, Ninth Revision (ICD-9) and Current Procedural Terminology (CPT) coding information.

Exclusions

Unspecified

Exceptions

Documentation of medical reason(s) for not performing a baseline gonadotropin (luteinizing hormone [LH] or follicle-stimulating hormone [FSH]) measurement within six months prior to initiating testosterone therapy (e.g., karyotype diagnosis of Klinefelter's syndrome, prior history of total hypophysectomy, history of bilateral orchiectomy or anatomically confirmed congenital absence of testes)

Exclusions/Exceptions

not defined yet

Numerator Inclusions/Exclusions

Inclusions

Patients who have a baseline gonadotropin (luteinizing hormone [LH] or follicle-stimulating hormone [FSH]) measurement performed within six months prior to initiating testosterone therapy

Exclusions

Unspecified

Numerator Search Strategy

Fixed time period or point in time

Data Source

Administrative clinical data

Electronic health/medical record

Paper medical record

Type of Health State

Does not apply to this measure

Instruments Used and/or Associated with the Measure

Unspecified

Computation of the Measure

Measure Specifies Disaggregation

Does not apply to this measure

Scoring

Rate/Proportion

Interpretation of Score

Desired value is a higher score

Allowance for Patient or Population Factors

not defined yet

Standard of Comparison

not defined yet

Identifying Information

Original Title

Measure #2: baseline gonadotropin (LH or FSH) measurement.

Measure Collection Name

Diagnosis, Treatment, and Follow-up of Men with Androgen Deficiency Physician Performance Measurement Set

Submitter

The Endocrine Society - Disease Specific Society

Developer

The Endocrine Society - Disease Specific Society

Funding Source(s)

Internal funding and commercially supported

Composition of the Group that Developed the Measure

Work Group Members:

James Rosenzweig (*Chair*)
David Aron, MD
Shalender Bhasin, MD
Jane Cauley, MD, PhD
J. Quentin Clemens, MD
David Cooper, MD
George Dailey, MD
Michael Holick, MD, PhD
Alvin Matsumoto, MD
George Merriam, MD
Abraham Morgentaler, MD
Stephanie Page, MD, PhD

Work Group Staff:

Stephanie Kutler, Director of Quality Improvement (ES)
Becky Kresowik, Measure Development Consultant

Financial Disclosures/Other Potential Conflicts of Interest

The Society's Diagnosis, Treatment, and Follow-up of Men with Androgen Deficiency Performance Measures were developed by a Society work group, under guidance of the Society's Performance Measures Sub-Committee (PMSC) and the Clinical Affairs Core Committee (CACC). All persons in control of content, including all members of the various Society committees, subcommittees and faculty workgroups, as well as staff, disclose all relevant financial relationships of the individual or spouse/partner that have occurred within the last 12 months with any commercial interest(s) whose products or services are related to the content. Financial relationships are defined by remuneration in any amount from the commercial interest(s) in the form of grants; research support; consulting fees; salary; ownership interest (e.g., stocks, stock options, or ownership interest excluding diversified mutual funds); honoraria or other payments for participation in speakers' bureaus, advisory boards, or boards of directors; or other financial benefits. Any conflicts of interest are resolved prior to the individual's control of content, using the peer-review process as the primary mechanism to resolve conflicts.

At the time of Measure Development - the following Androgen Deficiency Measure Task Force members reported no relevant financial relationships:

David Aron, MD
Associate Chief of Staff/Education, Department of Veteran Affairs

Jane Cauley, MD
Professor, University of Pittsburgh

J. Quentin Clemens, MD
Associate Professor of Urology, University of Michigan

David Cooper, MD
Director, Thyroid Clinic, Professor of Medicine, John Hopkins University School of Medicine

George Dailey, MD
Endocrinologist, Diabetes & Metabolism, Scripps Clinical Medical Group

Alvin Matsumoto, MD
Professor, Department of Medicine
Acting Head, Division of Gerontology & Geriatric Medicine
University of Washington School of Medicine

George Merriam, MD
Physician; Deputy ACOS/R&D, Department of Veterans Affairs

Abraham Morgentaler, MD
Associate Clinical Professor of Urology, Harvard Medical School

Stephanie Page, MD, PhD
Associate Professor, University of Washington School of Medicine

James Rosenzweig, MD
Director of Diabetes Services, Boston Medical Center

At the time of Measure Development - the following Androgen Deficiency Measure Task Force members reported relevant financial relationships:

Shalender Bhasin, MD
Professor & Section Chief, Boston University Medical Center
Investigator & Consultant, Abbott

Michael Holick, MD, PhD
Professor of Medicine, Physiology and Biophysics, Boston University School of Medicine
Investigator & Consultant, Quest; P&G; Novartis; Amgen

Endocrine Society staff associated with the development of content reported no relevant financial relationships.

Adaptation

This measure was not adapted from another source.

Date of Most Current Version in NQMC

2012 May

Measure Maintenance

The developer aims to review the module clinical content and modify as appropriate, based on research and revised clinical practice guidelines

Date of Next Anticipated Revision

2016 Dec

Measure Status

This is the current release of the measure.

The measure developer reaffirmed the currency of this measure in June 2016.

Measure Availability

Source available from [The Endocrine Society Web site](#) .

For more information, contact The Endocrine Society at 2055 L. Street, NW, Suite 600, Washington, DC 20036; Phone: 202-971-3636; Fax: 202-736-9705; Web site: www.endocrine.org .

NQMC Status

This NQMC summary was completed by ECRI Institute on April 10, 2015. The information was verified by the measure developer on May 18, 2015. The information was reaffirmed by the measure developer on June 30, 2016.

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For more information, contact the Endocrine Society at 2055 L. Street, NW, Suite 600, Washington, DC 20036; Phone: 202-971-3636; Fax: 202-736-9705; Web site: www.endocrine.org .

Production

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Endocrine Society. Diagnosis, treatment, and follow-up of men with androgen deficiency. Physician performance measurement set. Washington (DC): Endocrine Society; 2012 May. 17 p. [31 references]

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